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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/086,972	03/01/2002	Robert M. Hoek	DX0936KB	1945

7590 06/17/2005

DNAX Research, Inc.
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Palo Alto, CA 94304-1104

EXAMINER

OUSPENSKI, ILIA I

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 06/17/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/086,972

Applicant(s)

HOEK ET AL.

Examiner

ILIA OUSPENSKI

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 05/02/2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 4,5,10,18,21 and 22 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 4,5,10,18,21 and 22 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. Applicant's amendment, filed 05/02/2005, is acknowledged.

Claims 1 – 3, 6 – 9, 11 – 17, and 19 – 20 have been cancelled.

Claims 21 and 22 have been added.

Claims 4, 5, 10, and 18 have been amended.

Claims 4, 5, 10, 18, 21 and 22 are pending.

2. This Office Action will be in response to applicant's arguments, filed 05/02/2005.

The rejections of record can be found in the previous Office Action, mailed 02/02/2005.

The text of those sections of Title 35 USC not included in this Action can be found in a prior Action.

It is noted that New Grounds of Rejection are set forth herein.

3. The amendment filed 05/02/2005 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: "The present application is a divisional application of then copending USSN 09/547,432 ... which is incorporated herein by reference."

Applicant is required to cancel the new matter in the reply to this Office action.

An incorporation-by-reference statement added after the filing date of an application is not permitted because no new matter can be added to an application after its filing date. See 35 USC §132(a). If an incorporation-by reference statement is included in an amendment to the specification to add a benefit claim after the filing date of the application, the amendment would not be proper. When a benefit claim is submitted after the filing of an application, the reference to the prior application cannot include incorporation-by-reference statement of the prior application. See Dart Industries v. Banner, 636 F.2d 684, 207 USPQ 273 (C.A.D.C. 1980). Therefore, the Office will not grant a petition to accept a benefit claim that includes an incorporation-by-reference statement of a prior application, unless the incorporation-by-reference statement was submitted on filing of the application. See USPTO OG Notices: 1268 OG 89 (18 March 2003).

4. Applicant's amendments to the Title, Abstract, and Specification of the disclosure have obviated the rejections of record set forth in the Office Action mailed 02/02/2005.

5. Applicant's cancellation of claim 7 has rendered moot the objection of record set forth in the Office Action mailed 02/02/2005.

6. Applicant's amendment has obviated the rejection of record under **35 USC 112, second paragraph**, set forth in the Office Action mailed 02/02/2005.

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7. Claim 4 is rejected under **35 U.S.C. 112, second paragraph**, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 4 is indefinite in the recitation of "said animal," because the recitation lacks antecedent basis in the base claim 21. Therefore, one of ordinary skill in the art would not be reasonably apprised of the metes and bounds of the invention.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

8. Applicant's amendment has obviated the rejection of record under **35 USC 112, first paragraph**, set forth in the Office Action mailed 02/02/2005.

9. Claims 18 and 22 are rejected under **35 U.S.C. 112, first paragraph**, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *This is a New Matter rejection.*

Applicant's amendment asserts that no New Matter has been added and points to originally filed claims 1 and 3 for support for the newly added limitation "activation of a microglial cell in neural tissue," and "contacting the microglial cell in the tissue." However, the specification does not appear to provide an adequate written description these limitations.

It is noted that the originally filed claim 5, and the specification on page 4, lines 23 – 24, contains a phrase "wherein the sign or symptom is in neural tissue." However,

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this is not seen as providing adequate support under 35 USC 112, first paragraph, for the recitations of "activation of a microglial cell in neural tissue," and "contacting the microglial cell in the tissue."

The instant claims now recite limitations which were not clearly disclosed in the specification and claims as filed, and now change the scope of the instant disclosure as filed. Such limitations recited in the present claims, which did not appear in the specification or original claims, as filed, introduce new concepts and violate the description requirement of the first paragraph of 35 U.S.C. 112.

Applicant is required to cancel the New Matter in the response to this Office Action. Alternatively, Applicant is invited to clearly point out the written support for the instant limitations.

10. Applicant's amendment has obviated the rejection of record of claims 1, 4 – 9, and 16 – 18 under **35 USC 102(b)** as being anticipated by Borriello et al.

11. Claims 4, 5, 10, and 18 stand rejected, and newly added claims 21 and 22 are rejected under **35 U.S.C. 102(e)** as being anticipated by Gorczynski (US Patent 6,338,851; see entire document).

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that Gorczynski does not teach inhibiting the activity of microglial cells to treat neurodegeneration, and thus does not enable one skilled in the art to recognize that OX2 can mediate microglial activity in neural tissues.

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This is not found persuasive, because Gorczynski teaches administering OX2 protein to treat multiple sclerosis (a neurodegenerative condition) (e.g. column 7 lines 4 – 31). These teachings inherently encompass contact between the administered OX2 protein and cells of the animal, including microglial cells. Since inhibiting activation of microglial cells is an inherent property of the OX2 protein, the reference teachings anticipate the instant claimed invention.

The rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims.

The rejection of record is reiterated herein for Applicant's convenience.

Gorczynski teaches a method of preventing or treating an autoimmune disease by administering OX2 protein (see entire document, in particular, e.g. column 2 lines 43 – 49). Gorczynski further teaches that OX2 suppresses immune responses inhibiting IL2 production and generation of cytotoxic T cells (e.g. column 42 first paragraph), i.e. OX2 inhibits activation of T lymphocytes. Since T lymphocytes are leukocytes, it follows that OX2 inhibits activation of leukocytes. Since Gorczynski teaches administering OX2 protein to an animal, the method inherently comprises the step of OX2 contacting any cell type available in said animal, including myeloid lineage cells.

Gorczynski further teaches that autoimmune diseases which can be treated by administering OX2 include multiple sclerosis (column 7 lines 4 – 31). Gorczynski also teaches that pharmaceutical compositions of OX2 protein may additionally contain immunosuppressive drugs (column 10 lines 6 – 24), and exemplifies immunosuppressive drugs by corticosteroids (i.e. steroids) (column 1 lines 39 – 44).

Taken together, these teachings amount to a method of inhibiting activation of a leukocyte in an animal by administering OX2 protein either alone or in combination with steroids, to treat multiple sclerosis, wherein administering OX2 inherently includes contacting myeloid lineage cells.

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It is noted that multiple sclerosis is inherently a neurodegenerative disorder, and that its signs or symptoms inherently occur in neural tissue.

Thus the reference teaching anticipates the claimed invention.

12. Claims 4, 5, 10, and 18 stand provisionally rejected, and newly added claims 21 and 22 are provisionally rejected under the judicially created doctrine of **obviousness-type double patenting** as being unpatentable over claim 1 of copending Application USSN 10/741,430, published as US Pat. Pub. 2004/0213783. Although the conflicting claims are not identical, they are not patentably distinct from each other for reasons set forth herein.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments have been fully considered but have not been found convincing.

Applicant argues that the '430 application does not claim the use of OX2 protein to inhibit microglial cells in order to treat neurodegeneration, thus the present invention is allegedly patentably distinct from the '430 application.

This is not found persuasive, because claim 1 of the '430 application is directed, inter alia, to treating a subject (i.e. administering to a subject) CD200 (OX2) protein. Thus the claim inherently encompasses contact between the administered OX2 protein and cells of the subject, including microglial cells. Since inhibiting activation of microglial cells is an inherent property of the OX2 protein, the instant claims are directed to an invention not patentably distinct from claim 1 of commonly assigned Application USSN 10/741,430.

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The provisional rejection of record is maintained for the reasons of record, as it applies to the amended and newly added claims.

The U.S. Patent and Trademark Office normally will not institute an interference between applications or a patent and an application of common ownership (see MPEP § 2302). Commonly assigned USSN 10/741,430, discussed above, would form the basis for a rejection of the noted claims under 35 U.S.C. 103(a) if the commonly assigned case qualifies as prior art under 35 U.S.C. 102(e), (f) or (g) and the conflicting inventions were not commonly owned at the time the invention in this application was made. In order for the examiner to resolve this issue, the assignee can, under 35 U.S.C. 103(c) and 37 CFR 1.78(c), either show that the conflicting inventions were commonly owned at the time the invention in this application was made, or name the prior inventor of the conflicting subject matter.

A showing that the inventions were commonly owned at the time the invention in this application was made will preclude a rejection under 35 U.S.C. 103(a) based upon the commonly assigned case as a reference under 35 U.S.C. 102(f) or (g), or 35 U.S.C. 102(e) for applications filed on or after November 29, 1999.

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the

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shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Conclusion: no claim is allowed.

15. Any inquiry concerning this communication or earlier communications from the examiner should be directed to ILIA OUSPENSKI whose telephone number is 571-272-2920. The examiner can normally be reached on Monday-Friday 9 - 5.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on 571-272-0841. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

ILIA OUSPENSKI
Patent Examiner
Art Unit 1644

June 13, 2005

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6/14/05